REMARKS

This paper is a response to the outstanding office action of June 9, 2009. After amendment, claims 1-3, 6-7 and 89-102 are pending in the present application. Claims 94-102 were previously added as new claims to provide further dependent claims reflective of the restricted invention. In claim 1, Applicants previously amended the term *comprising* which is an open term to the term *consisting essentially of*, a term which is more limited in scope. Notwithstanding the Examiner's comments regarding same, the term *consisting essentially of* is used and is meant to describe biodegradable crosslinked diblock polymers according to the present invention which contain diblock (AB) polymers which are crosslinked and avoid substantial quantities of multiblock polymers within the polymer backbone which is crosslinked and are biodegradable. The compositions are consistent with use in biological systems and in certain preferred aspects are useful in inhibition the formation or reducing the likelihood of adhesions forming subsequent to surgical procedures. Claims 4-5 and 8-88 were previously canceled without prejudice as was all previously canceled subject matter. It is respectfully submitted that the amended claims as presented herein meet the requirements of 35 U.S.C. and are clearly patentable over the art of record.

A review of the present claims in comparison to the disclosures cited against the instant application evidences that the presently claimed compositions are patentable over the disclosures of Ebato, et al., US Patent no. 5,525,671 ("Ebato"), in view of Gref, et al., published as WO 95/03357 ("Gref"). Indeed, a fair reading of those disclosures suggests that a combination of those references actually *teaches away* from the presently claimed invention.

The Examiner has rejected pending claims 1-3, 6, 7 and 89-102 under 35 U.S.C. §103 as being invalid over Ebato, inview of Gref for reasons which have been articulated in the June 9, 2009 office action. For the reasons which are detailed hereinbelow, Applicants respectfully submit that theExaminer has not made out a cogent case that the pending claims are unpatentable

over the cited prior art.

The Examiner has rejected claims 1-3, 6-7 and 89-102 under 35 U.S.C. §103(a) as being unpatentable over the disclosure of Ebato, in view of Gref for the reasons which are set forth in detail on pages 4-6 of the office action. It the Examiner's view that Ebato teaches lactide copolymers which contain lactide and hydroxyl-containing polymer(s) which include diols such as ethylene glycol and propylene glycol. The polymers may further comprise a polyfunctional isocyanate or acid anhydride. The polymers of Ebato are crosslinked to increase molecular weight. The Examiner notes that Ebato does not disclose that the hydroxyl containing polymer is encapped as is the case in the present invention.

Gref is cited by the Examiner as disclosing biodegradable nanoparticles. The polymeric materials of Gref include polymers which include diblocks of PEG-PGLA. From this description and the description of Ebato it is the Examiner's view that the presently claimed invention is unpatentable because it "would have been obvious to one of ordinary skill in the art to combine the teachings of Ebato, et al. and Greg [sic], et al. and utilize end-capped polyethylene glycol such as monomethoxylpolyethylene glycol." The Examiner further argues that the person of ordinary skill would have been motivated to utilize an end-capped PEG in order to form diblock copolymers as utilizing EPG comprising both ends with free hydroxyl groups forms triblock copolymers. The Examiner concludes by further arguing that it would have been obvious to the person of ordinary skill to combine the teachings of Ebato and Gref and utilize the cross linking agent hexamethylene diisocyanate in order to manipulate the lactide copolymer as taught by Ebato. Applicants respectfully traverse the Examiner's rejection of the presently pending claimed invention.

The present invention is directed to novel crosslinked diblock polymers *consisting essentially of* AB diblocks which are crosslinked, where A is a polyester block and B is a polyether (poly)oxyalkylene block which is end-capped with a non-reactive group. By using the

term *consisting essentially of* as that term is given its ordinary meaning, compositions according to the present invention provide AB diblock polymeric compositions which are crosslinked. These polymeric diblock compositions are useful primarily in medical applications as they take advantage of a biodegradable polyester block to which is bonded a polyoxyalkylene block. As claimed, the present invention clearly distinguishes over the teachings Ebato and Gref inasmuch as Ebato *avoids* the formation of diblock polymers as in the present invention and Gref *avoids crosslinking* in order to limit the size of the polymeric compositions so that they will be useful as nanoparticles. As discussed hereinbelow, the person of ordinary skill would not be motivated to combine the teachings of Ebato and Gref to produce the present invention because such a combination would work at *cross purposes* to the underlying rationale for the teachings of Ebato and Gref.

Note that Ebato is primarily directed to a *method* of continuously producing a lactide copolymer to produce polymers of varying properties and *high molecular weight*. Ebato only mentions polyoxyalkylene ethers in conjunction with its status as a diol in producing polymers using the newly described continuous process. Ebato does not disclose an end-capped polyethylene glycol as in the present invention. As one of ordinary skill recognizes, the use of a polymeric diol, as opposed to an end-capped polyoxyalkylene as is used in the present invention does not produce *diblocks* and will not result in the production of diblocks as in the present invention. Indeed, the only chemistry which Ebato mentions which is even related to the presently claimed compositions relies on polyoxyalkylene polymer as a *diol,* which, when polymerized with lactide as otherwise described in Ebato, would produce a ***triblock*** polymeric material (lactide reaction at each alcohol position), not a diblock polymeric material as is used in the present invention. In addition to the fact that the composition characteristics of Ebato are not even emphasized (rather the *process* of continuously producing a lactide polymer is emphasized), is the fact that the compositions described by Ebato do not produce compositions similar to the present invention and are *by design* completely different from the present invention.

Unlike the present invention, where diblock formation is provided to control and *limit* the molecular weight with the diblock consistent with the use of the present invention in medical applications, the compositions of Ebato which contain polyoxyalkylene ethers, are *triblock* copolymers (by virtue of the chemistry of production) and are manufactured to produce a high *molecular weight.* There is no motivation in Ebato to cap a polyoxyalkylene glycol because there is no motivation to limit molecular weight as occurs in a diblock polymer, given that motivation in Ebato is to produce polymers of *high molecular weight.* In particular, a description of the products for which the various lactide containing polymers of Ebato are produced include packaging materials (bags, films or binding tape), industrial articles, fibers, agricultural multi-films, containers for foods, curing sheet for concrete, pots for seedlings and industrial materials and moldings. Even a description of the products for which the Ebato polymers are prepared evidences that Ebato was synthesizing high molecular weight polymeric materials which are consistent with triblock lactide-polyoxyalklyene-lactide polymers, not diblock polymers as are claimed in the present invention. To suggest that one of ordinary skill relying on Ebato would substantially modify the polyoxyalkylene polymers and end-cap those polymers to produce compositions which would be viewed as being less desirable by Ebato (by virtue of the *lower molecular weight* of a diblock compared to a triblock) is not in keeping with the common sense motivations which are described in or may be readily gleaned from Ebato. Indeed, for Ebato to use the presently claimed compositions would be for Ebato to try to produce a polymeric composition of *lower,* **not** *higher* molecular weight, a composition which Ebato would view as inferior to the products described. Such an approach would be counterintuitive and contraindicated. Thus, Applicants respectfully submit that Ebato actually *teaches away* from the present invention.

Turning to the teachings of Gref, this reference clearly does not obviate the deficiencies of Ebato, but rather enforces the deficiencies of Ebato and the non-obviousness of the present invention. Gref is directed to polymeric materials which may be based upon diblock, triblock or multiblock polymers. The polymers of Gref are used to produce nanoparticles, i.e., compositions

of extremely limited size, in order to be useful as *carriers* of biologically active ligands. The polymers of Gref are maintained in a small molecular weight state in order to carrier biological ligands in the blood through the circulatory system of a patient to cells and organs. Gref does not disclose the polymeric materials according to the present invention and in particular, *teaches away* from the general concept of increasing the molecular weight of the polymeric materials by chain extending or crosslinking, an important feature of the present invention. Indeed, there is absolutely no motivation to increase the molecular weight and consequently, the size of the Gref disclosed polymers, because as carriers in the blood, the polymers are optimally of small size so as to enable passage through small circulatory vessels in enhancing delivery of covalently linked biologically active ligands. Gref neither discloses nor suggests crosslinking of diblock polymers, and indeed the person of ordinary skill would be taught away from such an approach, because such a measure would actually work at cross purposes to the objects of the Gref polymers, i.e., to facilitate the use of polymeric carriers to deliver biologically active ligands through the bloodstream of a patient. Increasing the size of the polymer would risk having a polymer unable to pass through small blood vessels and into cells to deliver bioactive, a measure which would provide an unworkable approach. Gref, consequently teaches away from the present invention.

Thus, the argument that one of ordinary skill would combine the teachings of Ebato with Gref to produce the presently polymeric compositions is simply not cogent. It is respectfully submitted that one of ordinary skill viewing Ebato would not even look to Gref to provide diblock polymers, because diblock polymers, as evidenced by the teachings of Gref, are useful to limit molecular weight and provide nanoparticles which may used to deliver bioactive ligands through a patient's bloodstream, a goal which runs completely counter to the motivations of Ebato, which is to produce industrial polymers of higher molecular weight. Also, suggesting that the Gref disclosed polymers should be crosslinked runs counter to the motivations of the Gref teachings, inasmuch as crosslinking such polymers would likely only result in potential complications in using the Gref polymers to deliver bioactive agents by substantially increasing

the molecular weight and size of the nanoparticles- the precise reason Gref *avoids* crosslinking in the first place.

Thus, the present invention represents an inventive concept which has found a favorable use for compositions which are neither disclosed nor suggested by the prior art. The object of the present invention resides, in part, in having polymeric materials of diblock character, the molecular weight of which may be carefully controlled, which are crosslinked to provide a material of a character useful in certain medical applications, in particular the inhibition of adhesion formation subsequent to a surgical procedure. The motivations which drove the inventors of the present invention to provide compositions of the present invention run completely counter to the teachings of the cited prior art and motivations which may be gleaned from those teachings. The present invention is completely counterintuitive to the prior art teachings and motivations gleaned therefrom. Consequently, the presently claimed invention is non-obvious and patentable over the cited prior art.

It is respectfully submitted that there can be no more cogent an argument for the non-obviousness of an invention where, as here, the prior art cited against the invention teaches that the presently claimed compositions should not be made because the invention *contravenes* the rationale and motivation for the teachings presented in the cited prior art. This is precisely why the presently claimed compositions are patentable over Ebato in view of Gref, and why a combination of those references does not in any way negative the present invention. If anything, the teachings of the prior art fully support the patentability of the present invention.

Consequently, for the reasons which are presented hereinabove, it is respectfully submitted that the claimed invention is in compliance with the requirements of 35 U.S.C. Applicants respectfully assert that the claims set forth in the amendment to the application of the present invention are now in condition for allowance and such action is earnestly solicited.

Applicants have neither added nor canceled any claims in this amendment. No fee is due for the presentation of this amendment. Small entity status pertains to this application. A petition for an extension of time is enclosed as is the fee. The Commissioner is authorized to charge any deficiency in fee or to credit any overpayment to deposit account 04-0838.

Respectfully submitted,

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Dated: October 6, 2009

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I hereby certify that this correspondence is being deposited with the U.S. Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on October 6, 2009.

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